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Long-Term Ibogaine Efficacy Study Initiated

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MONDAY, FEBRUARY 23 was not the beginning of just any old workweek, but an exciting and long-awaited day. On that day we facilitated the introduction of the first participant into an observational case series of the long-term efficacy of ibogaine-assisted therapy and associated interventions in participants with opiate addiction treated at the Iboga Therapy House (ITH) in Vancouver, Canada.

This MAPS-sponsored study is intended to gather information to evaluate whether ibogaine-assisted therapy helps opiate-dependent people stop using opiates, use less, or practice moderated use after the therapy. For one year after therapy we will be collecting data from participants in the study, enabling us to examine whether ibogaine-assisted therapy facilitates positive changes or improvements in quality of life that result in decreased harms associated

with chronic or mismanaged opiate use.

The road to getting this study approved and started was a long one. The protocol was originally designed as an outcome study, but it was later changed to an observational case study when the institutional review board expressed concerns that the initial design was too similar to a clinical trial. After three years, enduring numerous setbacks, the study is finally under way.

The conception of the study began in 2003, when MAPS Clinical Research Associate Valerie Mojeiko visited the ITH facility in Vancouver. At that time, the ITH was providing free ibogaine therapy to substance-dependent individuals as a response to the general lack of detoxification and treatment options. The five-day residential program provided an alternative to largely ineffective standard treatment models and provided a therapy based on the principles of harm reduction, health promotion, and psychedelic therapy. MAPS recognized the unique opportunity to study the outcomes of such a therapy as a potentially important contribution to the data available on the therapeutic uses of ibogaine. Thus, we began the process of developing a protocol for a study that would examine ibogaine-assisted therapy's potential in reducing harm and facilitating positive, healthy lifestyle changes.

**"...VANCOUVER
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The protocol design for the study is based on two primary and five secondary hypotheses. The primary hypotheses are that: 1) the ITH treatment program will result in changes in substance use, including decreases in average post-treatment scores on the Addiction Severity Index, with scores averaged over a one-year period; 2) the ITH treatment program will result in extended periods of abstinence post-treatment as quantified by average number of days post-treatment without use of opiates, and also by average time to first relapse.

The secondary hypotheses are that:

1. decreases in the Addiction Severity Index post-treatment will be correlated with high scores in both nadir and spiritual experiences as measured by the Peak Experience Profile;
2. the ITH treatment program will result in decreases in the Objective Opiate Withdrawal Scale and Subjective Opiate Withdrawal Scale immediately after treatment;
3. the ITH treatment program will result in extended periods of abstinence and/or extended periods of controlled drug use as quantified by amount of drugs used, and method and schedule of administration relevant to baseline;
4. average post-treatment scores of Addict Identity measured by the Social Identity Questionnaire-Substance Recovery (SIQ-SR) will be lower than pretreatment scores;
5. average posttreatment scores of Work, Recovery, Family and Religious Identity measured by the SIQ-SR will be higher than pretreatment scores.

Baseline data will be gathered prior to treatment at the ITH, with follow-up data gathered for one year following treatment. Most follow-up data will be gathered by telephone, since clients of the ITH program come from all over the United States and Canada. To verify participants' self reports, data from one or more of the participants' significant others will also be gathered by telephone.

Participants will be compensated \$10 for each study visit or phone interview, up to a maximum of \$160 for all 16 visits or interviews, to be paid at quarterly intervals throughout the course of the study and in payments valued at up to \$40 per quarterly payment, equaling the form of a gift certificate to a grocery store or restaurant of their choice.

It's worth noting that Vancouver has a uniquely innovative approach to drug policy, outlined in the Four Pillars Drug Strategy. This strategy is focused on developing humane approaches to drug use through prevention, treatment, harm reduction, and law enforcement.

Ibogaine-assisted therapy fits within the pillars of both harm reduction and treatment. It has the potential to provide an alternative method of rapid detoxification from substance withdrawal, particularly for those resistant to standard 12-step-based treatment options or those seeking to detoxify more rapidly from substitution-based pharmacotherapies such as methadone. Aside from providing symptomatic relief from withdrawal symptoms, ibogaine-assisted therapy can also provide psychotherapeutic benefits when used with proper intention in a safe and supportive environment.

"ASIDE FROM PROVIDING SYMPTOMATIC RELIEF FROM WITHDRAWAL SYMPTOMS, IBOGAINE-ASSISTED THERAPY CAN ALSO PROVIDE PSYCHOTHERAPEUTIC BENEFITS WHEN USED WITH PROPER INTENTION IN A SAFE AND SUPPORTIVE ENVIRONMENT."

In 2003 and 2004, the ITH collected preliminary anecdotal data from 20 people who received therapy at the facility. Though the outcome data was promising, the ITH was forced to end this preliminary research and the offering of free therapies in fall 2004 following the loss of program funding when Canadian philanthropist Marc Emery was extradited to the United States for the sale of cannabis seeds.

In early 2005, the ITH sought funding by writing a grant proposal to a new Canadian federal fund, the Drug Strategy Community Initiatives Fund (DSCIF), in hopes of reopening the facility and continuing the research. Although the submission was intriguing to the grant review board, the scope of the project was considered to be more than what the DSCIF could support at that time. In the meantime, the protocol development for the MAPS study continued, and the ITH began working to reopen the ITH as a nonprofit business.

These were challenging times, yet MAPS considered the study's potential too great to give up. In early 2006, MAPS submitted the first version of the study protocol to the institutional review board of IRB Services in Canada. Finally, on Aug. 11, 2006, the protocol received unconditional approval from the IRB. The ITH reopened its doors in March 2006 to continue offering ibogaine-assisted therapy in a beautiful new setting near the ocean and forest. It has made numerous improvements to its program and hired a new staff that includes a nurse, emergency medical technicians, a physician, facilitators, an art therapist, a substance counselor, and bodyworkers skilled in various healing modalities.

After more than three-and-a-half years of preparation, patience, and diligence, we are excitedly under way with the implementation of this groundbreaking study! Stay tuned for updates.

For more information about the study, see the protocol on the MAPS Web site: maps.org/ibogaine. For more information about the Iboga Therapy House visit: ibogatherapyhouse.net.

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